

REMARKS

Claims 1-18 have been canceled without prejudice or disclaimer and have been recast as claims 19-37. Claims 19-37 are supported throughout the specification as filed including, e.g., page 6, line 30 to page 8, line 1 and the original claims.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 1, 3-7, 9 and 14-16 under 35 U.S.C. 102(b) and the Rejection of Claims 12-13 under 35 U.S.C. 102(b) and/or 35 U.S.C. 103(a)

Claims 1, 3-7, 9 and 14-16 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Feldman et al. USPN 3,857,966 ("Feldman") taken in light of 5,356,637 ("Loosen"). Claims 12-13 stand rejected as anticipated by, or in the alternative as obvious over, Feldman. The Examiner cites Freeman as teaching hydrolysis of fish protein by reacting the protein first with an alkaline protease and then with a neutral protease, wherein the protein is inactivated after completion by raising the temperature, and the enzymes are preferably from *Bacillus*. The Examiner also alleges that claims 3-6 are "use terminology" and states that the discovery of a new property or use of a previously known composition, even when that property and use are unobvious, cannot impart patentability to claims to a known composition. With regard to claims 12-13, the Examiner states that these claims depend from a product-by-process claim and that the claimed characteristics cannot be measured by the Office. Loosen is cited as evidence that the alkaline protease Alcalase is derived from *Bacillus licheniformis*. This rejection is respectfully traversed.

As an initial matter, Applicants note that the amended claims are not in the format of product-by-process claims, and respectfully submit that any rejections alleged as a result of this format have been obviated thereby.

Moreover, the pending claims are directed to a method for producing a feed composition for feeding an animal, comprising a) hydrolysing fish meat with a neutral protease and an alkaline protease, and b) inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, and preparing the feed composition for intake by an animal, as well as a method of feeding an animal with a feed composition comprising a fish protein hydrolysate prepared by a method comprising a) hydrolysing fish meat with a neutral protease and an alkaline protease, and b) inactivating the proteases by heat treatment to obtain a feed

composition comprising a fish protein hydrolysate, and administering the feed composition to an animal.

Feldman does not teach or suggest use of fish protein hydrolysate in a feed composition. Thus, Feldman, taken alone or in light of Loosen, does not teach or suggest the pending claims.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102(b). Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 2, 10 and 14-17 under 35 U.S.C. 103

Claims 2, 10 and 14-17 stand are rejected under 35 U.S.C. 103 as being unpatentable over Feldman in view of Faith et al., USPN 3,697,285 ("Faith"). The Examiner relies on the teaching of Feldman as outlined above, and states that Feldman does not teach the removal of oil or that the fish is raw. The Examiner cites Faith as teaching hydrolysis of fish proteins and after enzymatic hydrolysis, separating the components, centrifuging and drying by spray or air or drum-drying, and hydrolyzing raw fish. The Examiner states that starting the hydrolysis using Feldman's disclosure and raw fish would not require more than ordinary skill. This rejection is respectfully traversed.

As previously stated, the pending claims are directed to a method for producing a feed composition for feeding an animal, comprising a) hydrolysing fish meat with a neutral protease and an alkaline protease, and b) inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, and preparing the feed composition for intake by an animal, as well as a method of feeding an animal with a feed composition comprising a fish protein hydrolysate prepared by a method comprising a) hydrolysing fish meat with a neutral protease and an alkaline protease, and b) inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, and administering the feed composition to an animal.

In contrast, neither Feldman nor Faith teach or suggest use of fish protein hydrolysate in a feed composition. Thus, neither Feldman nor Faith teach or suggest the pending claims.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claim 18 under 35 U.S.C. 103

Claim 18 stands rejected under 35 U.S.C. 103 as being unpatentable over Feldman in view of Freeman et al., USPN 4,473,589 ("Freeman") and Weeks et al., USPN 3,578,461

("Weeks"). The Examiner cites Feldman as above, but states that Feldman does not disclose that the protein hydrolysate is used in a method to feed animals. The Examiner cites Freeman as teaching the use of a hydrolysed fish protein as a feed supplement. The Examiner cites Weeks as teaching that hydrolysed protein can serve as a highly nutritious source of protein for animals, and concludes that the disclosures render obvious feeding animals with hydrolysed proteins. This rejection is respectfully traversed.

As previously stated, the pending claims are directed to a method for producing a feed composition for feeding an animal, comprising a) hydrolysing fish meat with a neutral protease and an alkaline protease, and b) inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, and preparing the feed composition for intake by an animal, as well as a method of feeding an animal with a feed composition comprising a fish protein hydrolysate prepared by a method comprising a) hydrolysing fish meat with a neutral protease and an alkaline protease, and b) inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, and administering the feed composition to an animal.

Moreover, the various studies cited in the background of the specification as filed show decreased growth rate of animals when substantial amounts of traditional protein sources are replaced with fish protein hydrolysates in animal feed. See especially, page 1, line 33 to page 2, line 7. In contrast, the present invention provides a fish protein hydrolysate which can replace substantial amounts of traditional protein sources in animal feed with beneficial effect on growth rate. To this end, the invention provides an animal feed composition comprising a fish protein hydrolysate produced with a neutral and an alkaline protease with subsequent inactivation of the enzymes by heat treatment. The beneficial effect on the growth rate is demonstrated in Examples 1-2.

For example, Example 1 shows that growth rate of salmon in fact increases with increasing substitution of fish meal with the fish protein hydrolysate of the invention. Surprisingly, the highest growth rate is obtained at the highest level of substitution, where 49% (based on crude protein) of the fish meal has been replaced by the fish protein hydrolysate of the invention. See, Example 1, especially Table 2 regarding weight of fish and specific growth rate of fish.

In addition, Example 2 shows that the substitution of soy meal with fish protein hydrolysate according to the invention has a beneficial influence on the growth of piglets. See, Example 2, especially Table 3 regarding growth rate and feed intake.

In contrast, none of Feldman, Freeman and/or Weeks, taken alone or in combination, teach or suggests a feed composition comprising a fish protein hydrolysate prepared by hydrolyzing fish meat with a neutral protease and an alkaline protease followed by inactivation by heat treatment, let alone a beneficial effect thereof.

In particular, as previously staged, Feldman does not relate to or mention possible use of fish protein hydrolysate in a feed composition.

Freeman is directed at a method for liquefying protein from animal tissue or single cell microorganisms but does not teach that any specific enzyme or enzyme combination is to be preferred (in fact, it is stated that "in general, any proteolytic enzyme may be employed" (column 2, line 60)), and especially does not teach the specific combination of a neutral and an alkaline protease for hydrolysis of fish meat. Further, even though the possible use of liquefied tissue or single cell microorganisms as a feed supplement is indicated, any beneficial effect of using such liquefied tissue/cells is not suggested, and in particular any beneficial effect on the growth rate of the animals to be fed is not at all hinted to.

Weeks discloses a method for preparing an edible nutritious proteinaceous material from non-edible protein material obtained from domestic animals (see, e.g., claim 1). Materials such as hair, nails, feathers, blood, entrails, lungs, and other non-edible materials are mentioned as possible raw materials (column 3, lines 19-29). In the examples the raw materials used are chicken feathers, hair, and offal obtained from butchering of cattle. It is clear from the whole teaching that the invention is directed at converting non-edible proteinaceous materials into materials useful for feed purposes. It is nowhere mentioned that fish meat, which is indeed an edible protein material, is useful as a raw material according to the Weeks. Further, the possibility of a beneficial effect on the growth rate is not suggested.

Finally, the Examiner has provided no clear rationale for one of skill in the art to combine the various teachings of Feldman, Freeman and/or Weeks in the way the claimed invention does. Accordingly, Applicants submit that even if a *prima facie* case is assumed to have been established in view of the cited references (which Applicants do not concede to be the case), such a *prima facie* case is overcome by the unexpected results achieved with the instant invention, i.e., the surprising and beneficial effects demonstrated where fish meal has been replaced by the fish protein hydrolysate of the invention.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. The Rejection of Claim 11 under 35 U.S.C. 103

Claim 11 stands rejected under 35 U.S.C. 103 as being unpatentable over Feldman in view of Weeks, Ikeda et al., USPN 4,036,993 ("Ikeda") and FR Patent 2,352,498 ("FR '498"). The Examiner cites Feldman as above, but states that Feldman does not show that fish meat was not heated above 70°C before hydrolysis. The Examiner cites Weeks as teaching heating to 37°C, Ikeda as teaching elevating the temperature to above 60°C, Freeman for teaching a temperature that is the equivalent of 76°C, and FR '498 for teaching heating fish to 40°C. The Examiner concludes that the ranges shown render obvious that determining such temperatures are within the ambit of routine skill. This rejection is respectfully traversed.

As previously stated, none of Feldman, Freeman and/or Weeks, taken alone or in combination, teach or suggests a feed composition comprising a fish protein hydrolysate prepared by hydrolyzing fish meat with a neutral protease and an alkaline protease followed by inactivation by heat treatment, let alone a beneficial effect thereof. The temperature treatments alleged by the Examiner to be disclosed in Feldman, Weeks, Ikeda, Freeman and/or FR '498 do not change this conclusion, and Applicants respectfully submit that the amended claims are not obvious in view of the cited references for at least this reason.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection of Claim 8 under 35 U.S.C. 103

Claim 8 stands rejected under 35 U.S.C. 103 as being unpatentable over Feldman in view of Xu et al., US Publication 2002/0004085 ("Xu"). The Examiner cites Feldman as above, but states that Feldman does not disclose that the neutral protease is obtained from *Bacillus amyloliquefaciens*. The Examiner cites Xu as teaching that Glutenase and Neutrase are enzymes obtained from *Bacillus amyloliquefaciens*, and states that to use such enzymes as the neutral protease of Feldman would have been obvious. This rejection is respectfully traversed.

As previously stated, Feldman, either alone or in combination with the variously cited references, does not teach or suggest a feed composition comprising a fish protein hydrolysate prepared by hydrolyzing fish meat with a neutral protease and an alkaline protease followed by inactivation by heat treatment, let alone a beneficial effect thereof. The enzyme sources recited in Xu does not change this conclusion, and Applicants respectfully submit that the amended claims are not obvious in view of the cited references for at least this reason.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. The Rejection of Claim 12-13 under 35 U.S.C. 103

Claims 12-13 stand rejected under 35 U.S.C. 103 as being unpatentable over Feldman in view of Blinkovsky et al., USPN 6,187,478 ("Blinkovsky") and Olsen, USPN 4,324,805 ("Olsen"). The Examiner cites Feldman as above, but states that Feldman does not disclose the degree of hydrolysis. The Examiner also states that claim 1 is written as a product-by-process claim. The Examiner cites Blinkovsky and Olsen as teaching degree of hydrolysis and concludes that it would have been obvious to aim at a high degree of hydrolysis. This rejection is respectfully traversed.

As previously stated, Feldman, either alone or in combination with the variously cited references, does not teach or suggest a feed composition comprising a fish protein hydrolysate prepared by hydrolyzing fish meat with a neutral protease and an alkaline protease followed by inactivation by heat treatment, let alone a beneficial effect thereof. The degree of hydrolysis recited in Blinkovsky and/or Olsen do not change this conclusion, and Applicants respectfully submit that the amended claims are not obvious in view of the cited references. Moreover, as also previously noted, the amended claims are not in the format of product-by-process claims, and respectfully submit that any rejections alleged as a result of this format have been obviated thereby.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

VII. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

Date: April 13, 2010

/Kristin McNamara, Reg. # 47692/
Kristin J. McNamara, Reg. No. 47,692
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212) 840-0097